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10/660,461	09/10/2003	Christopher J. Calhoun	MA9758P	4950

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EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,461	CALHOUN, CHRISTOPHER J.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination filed 1/11/2007.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Independent claim 1 and its depending claims 2-11 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**. The limitation "consisting essentially of one or more of a poly-lactide polymer and a copolymer of two or more different lactides" is considered new matter for two reasons. The limitation as currently written includes one **or more** polylactide polymers and two **or more** different lactides. The subject matter is not properly described as filed. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter. **It is suggested that applicant amends the claim**

to include a Markush group of the specific lactide polymers/copolymers supported by the specification.

Independent claim 1 and its depending claims 2-11 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the combination of a lactide and a copolymer, does not reasonably provide enablement for *more than one* polylactide polymer or a copolymer having *more than two* different lactides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review indicates that the instant specification is not sufficient to support the generic concept of a resorbable polymer base material consisting essentially of one or more of a polylactide polymer and a copolymer of two or more different lactides.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation, "the resorbable polymer base material comprises...", however claim 1 from which they depend recites the limitation, "a resorbable polymer base material consisting essentially of...". The claims fail to further limit the claimed invention as well as make it unclear whether poly(L-lactide-co-D,L-lactide) and poly-L-lactide are additional ingredients to the "group consisting of a poly-lactide polymer and a copolymer of two or more lactides"

or whether they are further limiting either the "poly-lactide polymer" or the "copolymer of two or more lactides".

Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended each of the claims to include a placement step (e.g. "placed to surround the apex of the heart"), however it is unclear if each of the claims intend for the placement step to be a secondary placement step to the original placement step (i.e. "placing the healing membrane adjacent to an opening in pericardial tissue") of claim 1 or if the placement step is further limiting the original placement step of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al. (USPN 5,795,584). Totakura teaches a surgical adhesion barrier and methods thereof comprising bioabsorbable polymers and copolymers including trimethylene carbonate, lactide and caprolactone, and mixtures thereof (abstract; column 2, lines 26-38; column 3, lines 36-51). The adhesion barrier is in the form of a substantially uniform, non-porous film and capable of comprising a medicinal agent including peptides (column 5, lines 25-52; column 10, lines 25-41). The barrier is also resilient, flexible and conformable allowing a surgeon to shape the device to fit the area of injury (column 4, lines 58-63; column 10, lines 54-60). In fact, Totakura teaches that the invention can be used for open general surgery and prevents formation of surgical adhesions at a surgical wound when the barrier is interposed between the surgical wound and the surrounding tissue (column 3, lines 7-9 and 19-22). Totakura further teaches the invention is generally used in the form of a sheet (i.e. substantially smooth) and may be shaped to conform to particular injury site and/or may be wrapped around an organ (column 10, lines 53-60). Totakura also teaches that the adhesion barrier has a thickness in the range of about 0.1-100 mils (column 5, lines 37-42), which translates to a thickness range of 2.54-2,540 microns because 1 mil is equivalent to one-thousandth of an inch or 25.4 microns (http://rel.intersil.com/docs/lexicon/M.html, page 3 of 6).

Totakura is silent to the particular placement of the membrane being at the opening of pericardial tissue; however, Totakura teaches the generic placement of the membrane between the site of injury and the surrounding tissue as well as the use of

the membrane for open general surgery and prevention of surgical adhesions. Totakura also cites the article, "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches" (Malm et al.) under the *Other Publications* section (page 2) of the patent, which suggests that pericardial adhesions as well as pericardial patches are well known in the art. Thus, one of ordinary skill in the art would be motivated to apply Totakura's generic teaching of placing the membrane between the site of injury and the surrounding tissue for the specific purpose of treating pericardial adhesions. A practitioner would reasonably expect the placement of a surgical adhesion barrier on the pericardium would effectively treat pericardial adhesions. Thus in Totakura, it would have been obvious to one skilled in the art at the time the invention was made to include the particular placement of the membrane being at the opening of pericardial tissue.

Totakura is silent to the particular resorption period of approximately 18 to 24 months; however, Totakura provides motivation to alter the rate of bioabsorption in the following disclosure,

> "...the rate of bioabsorption of each bioabsorbable layer can be varied by changing the chemical make up and/or thickness of each successive layer. Various bioabsorbable polymers, copolymers and/or blends thereof are known to have different rates of absorption. For example, bioabsorbable polymers having a high degree of crystallinity are absorbed less rapidly than bioabsorbable polymers having relatively higher amounts of amorphous regions. Thus, rates of bioabsorption can be engineered to fit particular needs" (column 9, lines 45-54).

One of ordinary skill in the art would have been motivated to achieve a resorption period of approximately 18 to 24 months by varying the chemical make up or thickness of the barrier in order to, for example, continue to elute a medicinal agent directly at the site of implantation depending on the needed treatment regime. A practitioner would have

reasonable expectation that the adhesion barrier taught by Totakura would continue to release a therapeutic agent at the site of implantation for various durations including approximately 18 to 24 months. Thus in Totakura, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to alter the resorption rate of the adhesion barrier to approximately 18 to 24 months.

Totakura is silent to sterile packaging; however, it is the position of the examiner that it is well known in the art that the surgical materials are sterilized prior to packaging or while packaged by way of, for example, irradiation. One would be motivated to provide the membrane in a sterile package for two main reasons: 1) ease of storage and transportation and 2) reduce the chance of infection in a patient. Thus, in Totakura it would have been obvious for one skilled in the art to include sterile packaging.

Response to Arguments

Applicant's amendment with respect to claim 21 has rendered the rejections under 35 USC 112, 1st and 2nd paragraphs moot. **Thus, the rejections of claim 21 under 35 USC 112, 1st and 2nd paragraphs have been withdrawn.**

Applicant's amendment with respect to claims 1-11 and 22-24 under 35 USC 112, 1st and 2nd paragraphs has been considered, however the amendment introduces new matter and scope of enablement issues for new reasons. An explanation can be found under the Maintained Rejections section of *this* Office Action. **Thus, the rejections of claims 1-11 and 22-24 under 35 USC 112, 1st and 2nd paragraphs have been maintained.**

Applicants did not address the rejections of claims 2, 3 and 22-24 under 35 USC 112, 2nd paragraph. **Thus, the rejections of claims 2, 3 and 22-24 under 35 USC 112, 2nd paragraph are maintained.**

Applicant's amendment with respect to the rejection of claims 1, 4-11 and 21 under 35 USC 103 has been rendered moot in part. **The rejection of claims 1, 4-11 under 35 USC 103 is withdrawn, however the rejection of claim 21 is maintained.** It is noted applicant does not address the specifics of independent claim 21 which vary significantly in scope with independent claim 1. Totakura teaches the claimed invention of claim 21 including the resorbable polymer base material. Totakura teaches a bioabsorbable material that is made of copolymers of carbonates and at least one other bioabsorbable polymer forming material (col. 3). Said carbonates include trimethylene carbonate and said bioabsorbable polymer forming material include lactides, caprolactones, and mixtures, blends and copolymers thereof (col. 3). The reference still reads on the claims (see Maintained Rejection section for details) and as such the rejection of claim 21 is maintained.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-

6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

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